OCT 2 1 2005

510(k) Summary of Safety and Effectiveness
Avon® PFJ Prosthesis

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Howmedica Osteonics Corp 325 Corporate Drive Mahwah, NJ 07430
For Information contact:	Vivian Kelly, Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5581 Fax: (201) 831-6038
Date Summary Prepared:	July 15, 2005

Device Identification

Proprietary Name:	Avon® Patello-femoral Joint Prosthesis
Common Name:	Patello-femoral arthroplasty
Classification Name and Reference:	Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis, 21 CFR 888.3540
Device Product Code:	OR (87) KRR

Description:

The Avon® Patello-femoral Joint (PFJ) Prosthesis was cleared for marketing in K010100, K020841 and K041160. The current system consists of cobalt-chromium femoral components available in four sizes (extra small, small, medium, and large), and all-polyethylene components available in various sizes (small, medium, and large) and styles. This 510(k) submission is a line extension to the Avon® Patello-femoral Joint Prosthesis to add additional styles of patellar components to the system and update the labeling.

Intended Use:

The Avon® Patello-femoral Prosthesis is a single-use device intended for replacement of the femoral side of the patello-femoral joint. Indications and are listed below.

Indications for Use

The Avon® Patello-femoral Joint Prosthesis is intended to be used in cemented patellofemoral arthroplasty in patients with degenerative arthritis in the distal femur and patella, patients with a history of patellar dislocation or patella fracture, or patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists. These components are single use only and are intended for implantation with bone cement.

Substantial Equivalence:

Avon® Patello-femoral Joint Prosthesis is substantially equivalent to the predicate Avon® PFJ Prosthesis in regards to design, materials, indications and operational principles. Testing demonstrated that the patellar components from the Duracon®, Triathlon® and Scorpio® Knee Systems are compatible with the femoral components in Avon® PFJ Prosthesis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 1 2005

Ms. Vivian Kelly
Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K051948
Trade/Device Name: Avon Patello-Femoral Joint Prosthesis
Regulation Number: 21 CFR 888.3540
Regulation Name: Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: KRR
Dated: October 14, 2005
Received: October 17, 2005

Dear Ms. Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051948

Device Name: Avon® PFJ Prosthesis

Indications for Use:

The Avon® Patello-femoral Joint Prosthesis is intended to be used in cemented patellofemoral arthroplasty in patients with degenerative arthritis in the distal femur and patella, patients with a history of patellar dislocation or patella fracture, or patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists.

These components are single use only and are intended for implantation with bone cement.

Prescription Use __X__ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051948